AMENDMENTS TO THE CLAIMS

1 (Previously presented). A method of generating a cell-based and humoral immune response to a target polypeptide in an animal in which an aqueous liposomal composition is administered subcutaneously or intramuscularly to the animal, the composition comprising liposomes suspended in an aqueous liquid having diameters in the range 100 to 2000 nm and comprising a lipid bilayer and an aqueous intravesicular space, the lipid bilayer being formed of liposome forming components and the aqueous intravesicular space comprising a polynucleotide in the form of a plasmid including a promoter and operatively encoding said target polypeptide wherein the target polypeptide is an antigen or a fragment of an antigen of an infectious microbe, whereby the said polynucleotide is delivered to and is expressed in target cells, to form target polypeptide and an immune response including an IgG response and Th1 and Th2 responses to the target polypeptide follows.

2 (Cancelled).

3 (Previously presented). A method according to claim 1 in which the plasmid includes ribosome binding sequences.

4 – 5 (Cancelled).

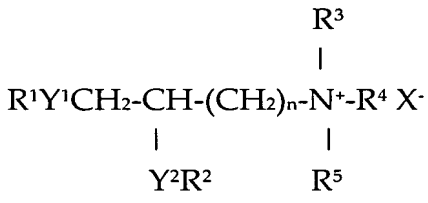
6 (Previously presented). A method according to claim 1 comprising the preliminary step of providing said aqueous liposomal composition by a process in which an aqueous suspension of empty liposomes formed from the liposome forming components is provided, the aqueous suspension of empty liposomes is mixed with said polynucleotide to form a mixed suspension, the mixed suspension is dehydrated to form a dehydrated mixture, and the dehydrated mixture is rehydrated in an aqueous

composition to form dehydration - rehydration vesicles containing the polynucleotide in the intravesicular space.

7 (Original). A method according to claim 6 in which the dehydration-rehydration vesicles are subjected to a micro fluidization step or extrusion.

8 (Original). A method according to claim 6 in which the dehydration is carried out by lyophilisation.

9 (Previously presented). A composition according to claim 38 in which the cationic component is a glyceride having the general formula



or an optical isomer thereof, wherein Y^1 and Y^2 are the same or different and are each -O- or O-C(O)- wherein the carbonyl carbon is joined to R^1 or R^2 as the case may be; R^1 and R^2 are independently an alkyl, alkenyl, or alkynyl group of 6 to 24 carbon atoms, R^3, R^4 and R^5 are independently hydrogen, alkyl of 1 to 8 carbon atoms, aryl or aralkyl of 6 to 11 carbon atoms; alternatively two or three of R^3, R^4 and R^5 are combined with the positively charged nitrogen atom to form a cyclic structure having from 5 to 8 atoms, where, in addition to the positively charged nitrogen atom, the atoms in the structure are carbon atoms and can include one oxygen, nitrogen or sulfur atom; n is 1 to 8; and X is an anion.

10 (Previously presented). A method according to claim 9 in which R^1 and R^2 individually have from 0 to 6 sites of unsaturation, and have the structure

CH_3-$(CH_2)_a$--(CH=CH--$CH_2)_b$--$(CH_2)_c$--

wherein the sum of a and c is from 1 to 23; and b is 0 to 6.

11 (Previously presented). A method according to claim 38 in which the cationic component is selected from the group consisting of DOTAP, BisHOP, DC-Chol and stearylamine.

12 (Original). A composition according to claim 1 in which the liposome forming components include a phosphatidyl ethanolamine.

13 (Previously presented). A method according to claim 1 in which the mean diameter of the liposomes in said aqueous liposomal composition is in the range 200 to 500 nm.

14 (Original). A method according to claim 1 in which said aqueous liposomal composition comprises 0.1 to 10 μg of polynucleotide per mg liposome forming components.

15 (Cancelled).

16 (Previously presented). A method according to claim 1 in which the composition is administered intramuscularly.

17 (Currently amended). A process for forming an aqueous suspension of liposomes having diameters in the range 100 to 2000 nm comprising the steps:

a) providing an aqueous suspension of small unilamellar vesicles formed from ~~liposomes~~ lipsome-forming agents selected from the group consisting of lipids, cholesterol and non-ionic and cationic surface active agents, wherein ~~including~~ at least one cationically charged component selected from cationic lipids and cationic

surface active agents is present in an amount whereby the small unilamellar vesicles have an overall cationic charge;

b) adding to the aqueous suspension of small unilamellar vesicles a polynucleotide in the form of plasmid DNA including a promoter and operatively encoding an immunogenic polypeptide which is an antigen or a fragment of an antigen of an infectious microbe useful to induce an immune response in an animal to form a mixed suspension in which the weight ratio of liposome forming components making up the small unilamellar vesicles in step (a) to the polynucleotide added in step (b) is in the range (50 to 10000):1;

c) dehydrating the mixed suspension to form a dehydrated mixture; and

d) rehydrating the dehydrated mixture to form an aqueous suspension of dehydration-rehydration vesicles containing said nucleic acid in ~~the~~ an intravesicular space thereof; and

e) optionally subjecting the aqueous suspension of dehydration-rehydration vesicles to a further step of microfluidisation whereby ~~the~~ said aqueous suspension of liposomes is produced.

18 (Original). A process according to claim 17 comprising the further step of subjecting the suspension of dehydration-rehydration vesicles to a separate step in which non-entrapped polynucleotide is separated from the aqueous suspension of dehydration-rehydration vesicles.

19 (Original). A process according to claim 18 in which the level of non-entrapped polynucleotide separated from the suspension is in the range 10 to 90% based on polynucleotide added in step (b).

20 (Original). A process according to claim 19 wherein the said level is in the range 15 to 80%.

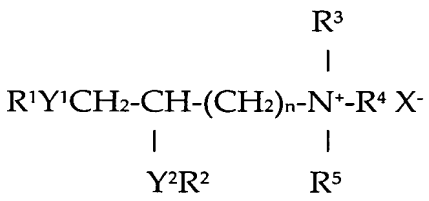
21 (Cancelled).

22 (Previously presented). A process according to claim 17 in which the plasmid includes ribosome binding sequences.

23 – 24 (Cancelled).

25 (Original). A process according to claim 17 in which the dehydrating is by lyophilisation.

26 (Previously presented). A process according to claim 17 in which the cationic component is a glyceride having the general formula



or an optical isomer thereof, wherein Y^1 and Y^2 are the same or different and are each -O- or O-C(O)- wherein the carbonyl carbon is joined to R^1 or R^2 as the case may be; R^1 and R^2 are independently an alkyl, alkenyl, or alkynyl group of 6 to 24 carbon atoms, R^3, R^4 and R^5 are independently hydrogen, alkyl of 1 to 8 carbon atoms, aryl or aralkyl of 6 to 11 carbon atoms; alternatively two or three of R^3, R^4 and R^5 are combined with the positively charged nitrogen atom to form a cyclic structure having from 5 to 8 atoms, where, in addition to the positively charged nitrogen atom, the atoms in the structure are carbon atoms and can include one oxygen, nitrogen or sulfur atom; n is 1 to 8; and X is an anion.

27 (Previously presented). A process according to claim 26 in which R^1 and R^2 individually have from 0 to 6 sites of unsaturation, and have the structure

$$CH_3\text{--}(CH_2)_a\text{--}(CH{=}CH\text{--}CH_2)_b\text{--}(CH_2)_c\text{--}$$

wherein the sum of a and c is from 1 to 23; and b is 0 to 6.

28 (Original). A process according to claim 17 in which the cationic component is selected from the group consisting of DOTAP, BisHOP, DC-Chol and stearylamine.

29 (Original). A process according to claim 17 in which the liposome forming components include a phosphatidyl ethanolamine.

30 (Original). A process according to claim 17 in which the small unilamellar vesicles in step (a) have a diameter in the range 100 to 400nm.

31 . (Original) A process according to claim 17 in which the dehydration-rehydration vesicles produced in step d) have diameters in the range 200 to 2000 nm.

32 – 33 (Cancelled).

34 (Previously presented). A composition for administration to an animal to induce a cell-based and humoral immune response comprising liposomes having diameters in the range 100 to 2000nm and having lipid-bilayers surrounding intravesicular spaces, which the lipid-bilayers are formed from liposome forming components selected from the group consisting of glycerides, cholesterol and non-ionic and cationic surface active agents including at least one cationic component selected from cationic surface active agents and cationic lipids in an amount to confer an overall cationic charge on the liposome forming components and the intravesicular space is

aqueous and contains a polynucleotide in the form of a plasmid having a promoter and operatively encoding an antigen or a fragment of an antigen of an infectious microbe, wherein the target microbe is a virus.

35 (Original). A composition according to claim 34 in which the virus is selected from hepatitis B, hepatitis C, influenza and human immunodeficiency virus.

36 (Previously presented) A composition according to claim 34 in which the polynucleotide encodes hepatitis B surface antigen or haemagglutinin.

37 (Original). A composition according to claim 34 which is an aqueous composition in which the liposomes are suspended in a pharmaceutically acceptable aqueous vehicle.

38 (Previously presented). A method according to claim 1 in which the liposome forming components include at least one cationically charged component in an amount such that the liposome forming components have an overall cationic charge.